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EXAMINER
RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 09/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/765,151	Applicant(s) GONZALES ET AL.	
	Examiner Anu Ramana	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/20/03* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrase "contact staining" in line 5 of claim 1 and line 4 of claim 15 is new matter. The specification does not describe what "contact staining" is and how it is effected by orally administrable compositions such as a pill, a capsule, a liquid and a chewable tablet.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 15-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Schlichte (US 6,303,102).

Regarding claims 15 and 19, Schlichte discloses a marker in combination with one or more treatment drugs or medicaments or "composition" applied either topically or orally wherein the marker is a pigment or a dye providing visual evidence for gauging both the application and

time since application of the medicament (col. 1, lines 7-11 and lines 50-54; col. 2, lines 21-30 and lines 52-56; and col. 3, lines 22-25). Schlichte also discloses that the marker can be any color and can be visible under a variety of lighting conditions, for example, visible light, infra-red light, ultra-violet light, monochromatic light or the like (col. 3, lines 17-21).

Regarding claims 16-18, Schlichte discloses that the markers are encapsulated or incorporated ("interspersed") in the composition (col. 4, lines 49-61).

Regarding claim 20, Schlichte further discloses that the presence or absence of the visible marker at the injection site or point of introduction of the medicament serves as an indicator that the recipient is clear of any residual medicament or drug, necessitating that the half-lives of the medicament and the marker be related or "comparable" (col. 3, lines 26-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlichte in view of Pather et al. (US 6,200,604).

Schlichte does not specifically disclose the type of dye or pigment used in the marker composition.

The use of dyes such as carmine red and FD&C dyes in oral compositions is well known. Pather et al. teach the use of carmine, beta-carotene and FD&C dyes in orally ingested compositions (col. 5, lines 1-6).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected carmine or FD&C dyes as the dye in the marker composition of Schlichte due to their suitability for oral consumption as taught by Pather et al.

Claims 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlichte in view of Kell (US 5,776,783).

Schlichte discloses a formulation or composition with multiple medications. Schlichte discloses that markers with unique coloring characteristics can be provided which remain in tissue for a predetermined period of time (several hours, days etc.) and then spontaneously disappear depending on the drug remaining in the system (col. 4, lines 44-48).

Schlichte does not disclose a marker associated with each medicament.

Kell teaches a medical formulation or oral composition which has multiple medications and separate markers associated with each medication in the formulation to monitor compliance with drug ingestion (col. 5, lines 20-34).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to provide multiple medications and unique markers associated with each medication in the composition of Schlichte wherein each marker has a unique coloring characteristic and residence time in the tissue, to monitor compliance with drug ingestion as taught by Kell.

Regarding claims 26 and 27, Schlichte discloses that a marker associated with a medicament can be any color and is visible under a variety of lighting conditions, namely, visible light, ultra-violet light etc. (col. 3, lines 16-21).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rittenburg et al. (US 6,068,981) in view of Schlichte.

Rittenburg et al. disclose a method of monitoring the compliance of a patient in following a therapeutic or medication regimen wherein the method includes the steps of providing a therapeutic compound and a detectable compound or marker that passes into tissue and detecting the marker in the tissue (col. 1, lines 22-35, lines 48-56).

Rittenburg et al. disclose that the marker passes into tissue in detectable form (col. 2, lines 65-67 and col. 3, lines 1-12).

Schlichte teaches a therapeutic compound with a marker that passes into tissue in the mouth by visibly coloring the tissue in the mouth ("oral/pharyngeal cavity") providing visual evidence for gauging both the application of and time since application of a medicament wherein

the color can be visually observed under a variety of lighting conditions such as visible light, ultra-violet light etc. (col. 2, lines 19-30 and col. 3, lines 22-25).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to use a detectable compound or marker that colors tissue in the mouth as taught by Schlichte in the method of Rittenberg et al. to provide visual evidence for gauging the application and time since application of the medicament.

Regarding claim 3, a placebo is well known in drug trials wherein the patient is told that the "placebo" is a drug and is treated like a drug. Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a marker combined with a placebo in a drug trial for introducing the "placebo" as an actual drug.

Regarding claim 6, although Schlichte discloses that the marker composition is visible under a variety of lighting conditions such as ultraviolet light, etc., Schlichte does not disclose specific wavelength ranges. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized violet-blue to blue light having a wavelength in a range of about 430 nm to 490 nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rittenberg et al. in view of Schlichte further in view of Pather et al.

The use of dyes such as carmine red and FD&C dyes in oral compositions is well known. Pather et al. teach the use of carmine, beta-carotene and FD&C dyes in oral compositions (col. 5, lines 1-6).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to use carmine, beta-carotene, FD&C dyes as a visible marker in the method of the combination of Rittenberg et al.-Schlichte since it is known in the art to use these dyes in orally ingested compositions.

Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rittenburg et al. (US 6,068,981) in view of Kell further in view of Schlichte.

Rittenburg et al. disclose a method of monitoring the compliance of a patient in following a therapeutic or medication regimen wherein the method includes the steps of providing a therapeutic compound and a detectable compound or marker that passes into tissue and detecting the marker in the tissue (col. 1, lines 22-35, lines 48-56). Rittenburg et al. also disclose that the marker passes into tissue in detectable form (col. 2, lines 65-67 and col. 3, lines 1-12).

Rittenburg et al. do not disclose multiple markers.

Kell teaches a medical formulation or oral composition, which has multiple medications and separate compliance markers, associated with each medication in the formulation to monitor compliance with drug ingestion.

See discussion for claims 23-27.

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a composition with multiple medicaments and multiple markers, each marker being associated with a specific medicament, in the Rittenburg-Kell combination wherein each marker has a unique coloring characteristic, a unique residence time and is detectable under a unique lighting condition (natural light or fluorescent light) to monitor ingestion of each separate drug as taught by Schlichte.

Response to Arguments

Applicants' arguments with respect to claims 1-27 in Paper No. 8 filed on June 20, 2003, have been considered but are not persuasive.

Regarding Applicants' arguments with respect to claim rejections under 102(e) of claims 15-20 on Pages 10-12 of the "REMARKS" section of Paper No. 8, the Schlichte patent discloses that a composition with a marker can be orally ingested and the color can appear in any tissue, for e.g., in the mouth, under the skin etc. (col. 3, lines 22-23). It is the Examiner's position that the Schlichte composition causes "contact staining" to the same extent as the Applicants' invention.

Regarding Applicants' arguments with respect to claim rejections under 103(a) of claims 21-22 on Pages 12-13 of Paper No. 8, Schlichte discloses that the orally administrable composition with markers is suitable for human consumption and that the marker is biodegradable and biologically tolerated to produce semi-permanent tell tales (col. 2, lines 52-56,

col. 3, lines 16-17 and col. 5, lines 13-34). Dyes such as FD&C dyes, indigo carmine and methylene blue are well known biologically tolerated and biodegradable dyes used in orally administered compositions (see Pather et al., Schlichte (col. 1, lines 61-66) and cited art). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a biologically tolerated and biodegradable dye such as FD&C dyes, indigo carmine and methylene blue as markers in the Schlichte composition, since it was known in the art that FD&C dyes, indigo carmine and methylene blue are biologically tolerated and biodegradable dyes.

Regarding Applicants' arguments with respect to claim rejections under 103(a) of claims 23-27 on Pages 13-15 of Paper No. 8, a patent is prior art for all that it teaches. In this case, the Kell reference provides the teaching of associating independent markers with separate medications for the purpose of monitoring compliance with ingestion of a specific drug.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicants' attention is directed to the following patents.

Smith (US 5,196,436): col. 7, line 59; col. 8, lines 16, 28, 44 and 62; and col. 9, lines 16, 33, 44 and 59.

US 5,458,879 (Singh et al.): col. 6, lines 55-58; col. 9, line 63; and col. 10, line 49.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR Anuradha Ramana
September 8, 2003

KEVIN SHAVER 9/8/03
SUPERVISORY PATENT EXAMINER
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